
Rotavirus Vaccine (Rotarix)

Explanation before Vaccination and Pre-vaccination Screening Questionnaire

製造販売元(輸入)

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『ロタウイルスワクチン (ロタリックス内用液) 接種説明書・予診票』の使い方

接種説明書(「保護者の方へ」)および予診票で1セットとなります。

接種説明書

Explanation before Rotavirus Vaccination (Rotarix)

Before administering Rotavirus vaccination (Rotarix), doctors should fully comprehend the health condition of the patient who is to receive it. Please read this explanation carefully and fill out the pre-vaccination screening questionnaire for Rotavirus vaccine (Rotarix) before undergoing a medical examination with the doctor. If the patient is an infant, his/her parents or guardians who know the health status of the infant well may answer the questions.

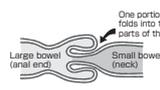
1 About Rotavirus Gastroenteritis

- Rotavirus gastroenteritis is a common viral gastroenteritis in children. Rotavirus, the cause of rotavirus gastroenteritis, is ubiquitous; regardless of hygiene, the infection is found worldwide.
- The illness often begins with explosive vomiting and leads to whitish watery diarrhoea. It can be accompanied by fever and such symptoms may last one week. Most patients are cared for at home and recover, but some children become dehydrated due to severe vomiting and diarrhoea. In more serious cases, the illness may lead to kidney failure, brain inflammation or encephalopathy. Hospitalisation is required for patients with severe cases.
- In Japan, rotavirus gastroenteritis peaks from the late winter to spring. The incidence of clinical illness peaks among children aged 3-24 months – the highest peak is at 7-15 months. Until the age of three months, infants are protected by maternal immunity and thus, if infected, the illness will be asymptomatic or only mild. However, the first infection after the age of three months is usually the most severe. In fact, rotavirus infection is the most common cause of severe acute gastroenteritis in infants and young children, and there is a report that one in ten children requiring an outpatient visit will ultimately require an inpatient visit.
- Children can be protected from severe rotavirus gastroenteritis by vaccination.

2 Indications for Rotarix

- Rotarix is a live, oral vaccine indicated for the prevention of rotavirus gastroenteritis (For oral use only. Not for injection).
- Rotarix was developed by the attenuation of a common human rotavirus strain in cell culture, reducing pathogenicity and is made as a syrupy liquid agent.
- Five major rotavirus strains, G1, G2, G3, G4, and G9, are responsible for most of the rotavirus gastroenteritis episodes worldwide. Rotarix is based on the G1 type, the most common human strain.
- The vaccine mimics natural infection and typically provides effective protection against the other four main strains.

3 The following infants should not receive vaccination:

- Infants with fever (temperature higher than 37.5°C).
 - Those with severe acute diseases (Postpone when there is symptoms of diarrhea and vomiting).
 - Those with a history of hypersensitivity to Rotarix.
 - Untreated infants with congenital gastrointestinal tract disorder that may increase the risk of intussusception* (such as Meckel's diverticulum).
 - Those with a history of intussusception.
 - Infants with severe combined immunodeficiency (SCID).
 - Infants under all other inappropriate conditions for vaccination.
- Intussusception (IS):** A condition occurring when one portion of the bowel folds into the remaining parts of the intestine that should be treated urgently. Regardless of vaccination, this condition is often observed in children less than 1 year old. IS causes a blockage of the intestine and the blood supply, which can lead to the death of intestinal tissues (necrosis). If IS is observed, the obstruction is typically cleared by flushing fluids, such as contrast agents and water, or air through the intestine from the anus. However, the more time passes from the start of the symptoms (e.g. 12 hours or longer), the higher the possibility that surgery will become necessary to remove the necrotized tissue.
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- Those with a history of convulsion.
 - Those with diseases associated with the abnormal immune function, those receiving immunosuppressive therapy, and those with a family history of congenital immunodeficiency (Vaccination in those immunocompromised may lead to viral proliferation and development of infection).
 - Those with gastrointestinal disorder.

保護者にお渡しください

予診票

Vaccination Screening Questionnaire for Rotavirus Vaccine (Rotarix)

Fill in the parts surrounded by thick solid lines, or enclose with O.

1st	2nd [Previous Time: / / (d/m/y)]	Body Temperature before interview	Degrees (°C)
〒		T E L () -	
Sex	M F	Birth Date	Born on / / (d/m/y)
Age		Age (weeks days)	

Vaccination Questionnaire	Answer	Doctor's Comment
Do you have the "Explanation before Rotavirus vaccination (Rotarix)"* *Explanation about the vaccination that you are going to receive today?	No Yes	
Do these statements apply? This is the first dose of rotavirus vaccination for the child. 1st dose. The first dose administered to the child was Rotarix.	No Yes	
Do the following questions about the child: 1. Have you any abnormal findings at delivery? 2. Have you any abnormal findings after birth? 3. Was he/she normally identified at an infant health check?	Yes No Yes No Yes No	Weight at birth (g)
4. Today? / the nature of the illness. (Details:)	Yes No	
5. Have you had diarrhoea today?	Yes No	
6. Has your child been ill within the last month? (/ ~ /) (Disease Name:)	Yes No	
7. Has a member or neighbor of the child had a disease such as measles, rubella, mumps within a month? (Disease Name:)	Yes No	
8. Has your child been vaccinated within four weeks? (/ ~ /) (Vaccine Name:)	Yes No	
9. Has your child had a congenital anomaly, heart, kidney, liver, digestive system, central nerve system deficiency, or any other diseases for which you have consulted a doctor? ()	Yes No	
10. Did the doctor who manages the above disease agree with today's vaccination?	Yes No	
11. Has your child repeatedly had an obvious fever, diarrhoea or other symptoms such as white spots inside the cheeks, or a prolonged recovery from illness?	Yes No	
12. Has your child ever had a seizure (spasm or fit) in the past? (When: /)	Yes No	
13. If you answered "yes" to the preceding question, did the child have a fever at that time?	Yes No	
14. Has your child ever had a rash or urticaria as a reaction to medications or food or become ill after eating foods or receiving certain medications? () (Food Name:)	Yes No	
15. Has your child ever had a family member or relative with a congenital immunodeficiency?	Yes No	
16. Has your child ever had a serious reaction to a vaccine in the past?	Yes No	
17. Has a member or relative of the child had a serious reaction to a vaccine in the past? ()	Yes No	
18. Has your child ever received a transfusion of blood or blood products or been given a medicine called gamma globulin in the past 6 months?	Yes No	
19. Do you have any questions about today's vaccination?	Yes No	

Doctor's Comment: Based on the above answers and the results of the interview, I have decided that the patient (can / should not) receive a vaccination today. I have explained the information regarding the benefits and side effects of vaccination (especially the risk and management of intussusception) and the support provided to people who experience adverse events associated with the vaccination to the parents/legal guardians. Signature or Name and Seal of Doctor: _____

For the Parent / Guardian: I fully understand all of the above, including the benefits, aim and side effects of vaccination (especially the risk and management of intussusception), having consulted with the doctor and having read the explanatory document. I (do / do not) agree to have the child vaccinated, taking into consideration past illnesses and present condition. Please circle your choice. Signature of Parent / Guardian: _____

Vaccine Name: Vaccine Name: Attenuated Human Rotavirus Vaccine, Oral Rotarix Manufacturer: GlaxoSmithKline K.K. Lot Number: _____	Dosage: Oral administration at a specified dose of 1.5 mL.	Institution / Doctor's Name / Date Administered: Institution: _____ Doctor's Name: _____ Date Administered: / / (d/m/y)
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This screening questionnaire is intended to ensure vaccination safety. Personal information is used only for the preliminary examination for immunization.

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1 About Rotavirus Gastroenteritis

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- The illness often begins with explosive vomiting and leads to whitish watery diarrhoea. It can be accompanied by fever and such symptoms may last one week. Most patients are cared for at home and recover, but some children become dehydrated due to severe vomiting and diarrhoea. In more serious cases, the illness may lead to kidney failure, brain inflammation or encephalopathy. Hospitalisation is required for patients with severe cases.
- In Japan, rotavirus gastroenteritis peaks from the late winter to spring. The incidence of clinical illness peaks among children aged 3-24 months - the highest peak is at 7-15 months. Until the age of three months, infants are protected by maternal immunity and thus, if infected, the illness will be asymptomatic or only mild. However, the first infection after the age of three months is usually the most severe. In fact, rotavirus infection is the most common causes of severe acute gastroenteritis in infants and young children, and there is a report that one in ten children requiring an outpatient visit will ultimately require an inpatient visit.
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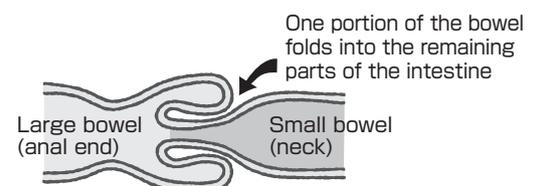
2 Indications for Rotarix

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3 The following infants should not receive vaccination:

- Infants with fever (temperature higher than 37.5°C).
- Those with severe acute diseases (Postpone when there is symptoms of diarrhea and vomiting).
- Those with a history of hypersensitivity to Rotarix.
- Untreated infants with congenital gastrointestinal tract disorder that may increase the risk of intussusception* (such as Meckel's diverticulum).
- Those with a history of intussusception.
- Infants with severe combined immunodeficiency (SCID).
- Infants under all other inappropriate conditions for vaccination.

*Intussusception (IS): A condition occurring when one portion of the bowel folds into the remaining parts of the intestine that should be treated urgently. Regardless of vaccination, this condition is often observed in children less than 1 year old. IS causes a blockage of the intestine and the blood supply, which can lead to the death of intestinal tissues (necrosis). If IS is observed, the obstruction is typically cleared by flushing fluid, such as contrast agents and water, or air through the intestine from the anus. However, the more time passes from the start of the symptoms (e.g. 12 hours or longer), the higher the possibility that surgery will become necessary to remove the necrotized tissue.



4 Consult a physician before vaccinating the following infants:

- Infants with underlying diseases such as cardiovascular/kidney/liver/blood diseases and development disorder.
- Those with a history of fever within 2 days after vaccination, or those with symptoms such as systemic exanthema, suggesting allergy.
- Those with a history of convulsion.
- Those with diseases associated with the abnormal immune function, those receiving immunosuppressive therapy, and those with a family history of congenital immunodeficiency (Vaccination in those immunocompromised may lead to viral proliferation and development of infection).
- Those with gastrointestinal disorder.

5 Dosage and Administration of Rotarix

- Rotarix is an oral, sweetened syrupy liquid vaccine.
- The vaccine is administered by directly inserting a tube with 1.5 ml dose into the mouth of the child*.
- The first dose should be administered to infants beginning at 6 weeks of age (it is recommended that the maximum age for the first dose is 14 weeks and 6 days). The 2-dose series should be completed by 24 weeks of age.
- There should be an interval of at least 27 days (4 weeks) between the first and second dose.

*Refrain from breastfeeding immediately prior (approximately 30 minutes) to vaccination with Rotarix.

6 Efficacy of Rotarix

- Rotarix mimics natural infection and provides effective protection against rotavirus gastroenteritis after two doses. Clinical trials have demonstrated efficacy against gastroenteritis caused by strains other than one contained in Rotarix.
- An overseas clinical trial showed that the vaccine's efficacy lasts at least three years.
- Protection against gastroenteritis caused by any organisms other than rotavirus is unknown. As with other vaccines, Rotarix does not work for all infants.

7 Adverse reactions of Rotarix

- Reported main adverse reactions within 30 days after administration from a clinical trial conducted in Japan were irritability (7.3%), diarrhoea (3.5%), cough/runny nose (3.3%). Other adverse reactions such as fever, anorexia, vomiting, gastrointestinal disorder and haematochezia were also reported.
- Some overseas clinical trials reported irritability, diarrhoea (1-below 10%, each), aerenterectasia (distended bowel) abdominal pains, and dermatitis (0.1-below 1%, each). Post-marketing surveys from home and abroad revealed that the risk of developing intussusception following vaccination with Rotarix may slightly increase.

● Relief System for Sufferers from Adverse Reactions to Vaccination

Despite proper use of Rotarix, if an adverse reaction occurs that causes disease that requires hospitalisation, or if disorders occur, you will be provided assistance under the Relief System for Sufferers from Adverse Drug Reactions. Depending on the severity of injury, fees for medical treatment, medical allowances, disability pension, survivor pension, lump-sum benefit for a bereaved family, will be paid after Food and Pharmaceutical Council deliberation. If your child shows any signs of distress or suspect symptoms, immediately seek medical attention.

8 Post-Vaccination Warnings

- As severe allergic symptoms may occur, please rest your child for at least 30 minutes after vaccination without returning home.
- On the day of vaccination, prevent the child from excessive activities.
- Monitor the child's health status and look carefully for any changes. If any abnormalities such as high fever or seizures appear, visit a doctor immediately.
- If symptoms of intussusception (IS) appear, including repetitive cycles of crying and crankiness, repeated vomiting, weakness and pale complexion, and bloody stools, visit a doctor immediately. In post-marketing surveys conducted in Japan and overseas, the possibility of a slight increase in the risk of developing IS was reported after rotavirus vaccinations. Therefore, attention should be paid to the appearance of symptoms of IS after vaccination (especially the week after the vaccination), regardless of the number of vaccinations administered.

If you visit another medical institution for symptoms of IS, please inform them that you have received Rotarix.

- Approximately one week after vaccination, shedding of vaccine virus in stools will occur, but the excreted virus is unlikely to cause gastroenteritis. However, for safety's sake, always wash your hands after contacting with children who have been vaccinated, e.g. after changing nappies. In particular, if you have a family with dysfunction of immune system, do wash your hands after contacting children who have been vaccinated.
- Rotavirus vaccine series should be completed with the same product. Safety and effectiveness have not been evaluated when Rotarix is administered as the first dose and another rotavirus vaccine is administered as the second dose, or vice versa.

Planned Date of Vaccination:	Institution/Clinic:
/ / (d/m/y)	
Time Administered ____ : ____ (a.m./p.m.)	

Pre-vaccination Screening Questionnaire for Rotavirus Vaccine (Rotarix)

Please fill out the parts surrounded by thick solid lines, or enclose with ○.

Times	1st	2nd [Previous Time: / / (d/m/y)]	Body Temperature before interview	Degrees (°C)
Address	〒		T E L	() -
Child's Name		M F	Birth Date	Born on / / (d/m/y)
Parent/Guardian's Name				Age (weeks days)

Vaccination Questionnaire	Answer		Doctor's Comment
Have you read the "Explanation before Rotavirus vaccination (Rotarix)," which is the explanation about the vaccination that you are going to receive today?	No	Yes	
Does either of these statements apply? This is the first dose of rotavirus vaccination for the child. This is the second dose. The first dose administered to the child was Rotarix.	No	Yes	
Please answer the following questions about the child. Weight at birth (g)			
Did the child have any abnormal findings at delivery?	Yes	No	
Did the child have any abnormal findings after birth?	Yes	No	
Was any abnormality identified at an infant health check?	Yes	No	
Is the child sick today? If so, describe the nature of the illness. (Details:)	Yes	No	
Does the child have diarrhoea today?	Yes	No	
Has the child been ill within the last month? (When: / ~ /) (Disease Name:)	Yes	No	
Has any family member or neighbor of the child had a disease such as measles, rubella, chickenpox or mumps within a month? (Disease Name:)	Yes	No	
Has the child been vaccinated within four weeks? (When: / ~ /) (Vaccine Name:)	Yes	No	
Does the child have a congenital anomaly, heart, kidney, liver, digestive system, central nerve disease, immune deficiency, or any other diseases for which you have consulted a doctor? (Disease Name:)	Yes	No	
Where relevant, did the doctor who manages the above disease agree with today's vaccination?	Yes	No	
Has the child repeatedly had an obvious fever, diarrhoea or other symptoms such as white spots on the tongue inside the cheeks, or a prolonged recovery from illness?	Yes	No	
Has the child ever had a seizure (spasm or fit) in the past? (When: /)	Yes	No	
If you answered "yes" to the preceding question, did the child have a fever at that time?	Yes	No	
Has the child ever had a rash or urticaria as a reaction to medications or food or become ill after eating certain foods or receiving certain medications? (Medicine Name:) (Food Name:)	Yes	No	
Does the child have a family member or relative with a congenital immunodeficiency?	Yes	No	
Has the child had a serious reaction to a vaccine in the past? (Vaccine Name:)	Yes	No	
Has any family member or relative of the child had a serious reaction to a vaccine in the past?	Yes	No	
Has the child received a transfusion of blood or blood products or been given a medicine called gamma globulin in the past 6 months?	Yes	No	
Do you have any questions about today's vaccination?	Yes	No	

Doctor's Comment	Based on the above answers and the results of the interview, I have decided that the patient (can / should not) receive a vaccination today. I have explained the information regarding the benefits and side effects of vaccination (especially the risk and management of intussusception) and the support provided to people who experience adverse events associated with the vaccination to the parents/legal guardians. Signature or Name and Seal of Doctor: _____
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For the Parent/Guardian	I fully understand all of the above, including the benefits, aim and side effects of vaccination (especially the risk and management of intussusception), having consulted with the doctor and having read the explanatory document. I (do / do not) agree to have the child vaccinated, taking into consideration past illnesses and present condition. Signature of Parent / Guardian: _____ * Please circle your choice.
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Vaccine Name	Dosage	Institution / Doctor's Name / Date Administered	Institution:
Vaccine Name: Attenuated Human Rotavirus Vaccine, Oral Rotarix Manufacturer: GlaxoSmithKline K.K. Lot Number:	Oral administration at a specified dose of 1.5 mL		Doctor's Name:
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